



DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA – 2016-0063]

Notice of Buy America Waiver

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice of Buy America Waiver.

SUMMARY: This notice provides NHTSA's finding with respect to a request to waive the requirements of Buy America from the New York Governor's Traffic Safety Committee (GTSC). NHTSA finds that a non-availability waiver of the Buy America requirement is appropriate for New York's purchase of a liquid chromatography-tandem mass spectrometry instrument using Federal highway traffic safety grant funds because that product is not produced in the United States.

DATES: The effective date of this waiver is **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Written comments regarding this notice may be submitted to NHTSA and must be received on or before: **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments may be submitted using any one of the following methods:

- **Mail:** Docket Management Facility, M-30, U.S. Department of Transportation, West Building, Ground Floor, Rm. W12-140, 1200 New Jersey Avenue, S.E., Washington, D.C. 20590.
- **Fax:** Written comments may be faxed to (202) 493-2251.

- **Internet:** To submit comments electronically, go to the Federal regulations website at <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- **Hand Delivery:** West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, S.E., between 9 am and 5 pm Eastern Time, Monday through Friday, except Federal holidays.

Instructions: All comments submitted in relation to this waiver must include the agency name and docket number. Please note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. You may also call the Docket at 202-366-9324.

FOR FURTHER INFORMATION CONTACT: For program issues, contact Barbara Sauers, Office of Regional Operations and Program Delivery, NHTSA (phone: 202-366-0144). For legal issues, contact Andrew DiMarsico, Office of Chief Counsel, NHTSA (phone: 202-366-5263). You may send mail to these officials at the National Highway Traffic Safety Administration, 1200 New Jersey Avenue, S.E., Washington, D.C. 20590.

SUPPLEMENTARY INFORMATION: This notice provides NHTSA's finding that a waiver of the Buy America requirement, 23 U.S.C. 313, is appropriate for the GTSC to purchase a liquid chromatography-tandem mass spectrometry device and its accessories for approximately \$400,000 using grant funds authorized under 23 U.S.C. 405(d). Section 405(d) funds are available for use by State highway safety programs to support effective programs to reduce driving under the influence of alcohol, drugs, or the combination of alcohol and drugs, including enforcement efforts. 23 U.S.C. 405(d). States may use Section 405(d) grant funds to improve blood-alcohol concentration testing and reporting and developing impaired driving information systems. *Id.*

Buy America provides that NHTSA “shall not obligate any funds authorized to be appropriated to carry out the Surface Transportation Assistance Act of 1982 (96 Stat. 2097) or [Title 23] and administered by the Department of Transportation, unless steel, iron, and manufactured products used in such project are produced in the United States.” 23 U.S.C. 313. However, NHTSA may waive those requirements if NHTSA finds “(1) that their application would be inconsistent with the public interest; (2) that such materials and products are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality; or (3) that the inclusion of domestic material will increase the cost of the overall project contract by more than 25 percent.” 23 U.S.C. 313(b).

The New York GTSC seeks a waiver to purchase a liquid chromatography-tandem mass spectrometry device (LC/MS/MS system) using Federal grant funds to be used by the New York State Police Forensic Investigation Center’s Toxicology Section (FIC) to analyze drugs in impaired driving case samples. The cost of a LC/MS/MS system is approximately \$400,000.

Liquid chromatography-tandem mass spectrometry is an analytical chemistry technique that combines the physical separation capabilities of liquid chromatography with the mass analysis capabilities of mass spectrometry. It is a technique that has very high sensitivity and selectivity that is oriented towards the separation, general detection and potential identification of chemicals of particular masses in the presence of other chemicals. This complex analytical technique involves two separate but connected instruments. These two instruments are each comprised of advanced scientific equipment, and this equipment is essential for the function of the entire LC/MS/MS system. The liquid chromatograph (LC) portion performs the chromatography part of the analysis that separates the drugs of interest from any interferences in the sample and passes them to a detector at known time intervals. Some essential pieces of

equipment within the LC system are the autosampler, which is used to inject all the samples, the pump used to control the mobile phase flow rate, the mixer used to precisely blend the mobile phases, and the degasser used to remove air from the mobile phase. The detector, a tandem mass spectrometer (MS/MS), uniquely identifies the drug by comparing its fragmentation pattern to a known library match. Some of the essential equipment within the MS/MS system are the rotary pump used to create a vacuum environment, the source used to fragment the drug into ions, the quadrupole mass analyzers used to filter the desired fragmented ions, the collision cell used to further fragment the filtered drug parent ions, and the ion detector (electron multiplier) used to detect every ion of selected mass that passes through the quadrupoles. In addition, a computer system with advanced software is used to control the entire LC/MS/MS instrument to provide more accurate reporting of the findings.

In support of its waiver request, GTSC states it seeks to purchase the LC/MS/MS instrument to replace a gas chromatography-mass spectrometry (GC/MS). GTSC adds that while GC/MS has long been an effective technique for the analysis of blood and urine for trace levels of drugs, LC/MS/MS has emerged in recent years as the preferred instrumentation. It adds that the benefits of LC/MS/MS are numerous, including increased sensitivity (which reduces sample consumption and lowers detection limits), fewer interferences from other drugs or metabolites (which can potentially reduce the number of inconclusive results), quicker and easier sample preparation, and faster run times. According to GTSC, these advantages can help to reduce overall turnaround time and give the analysts more time for additional casework. GTSC adds that the FIC is one of the only toxicology labs in the state that does not currently have an LC/MS/MS instrument and is unable to meet current driving under the influence detection guidelines for detection limits for many of the drug assays using a GC/MS instrument.

The GTSC claims that there are no LC/MS/MS instruments manufactured or assembled in the United States. It states that Agilent Technologies, Waters Corporation, AB Sciex (a subsidiary of Danaher Corporation), Thermo Fisher Scientific and Shimadzu are the only manufacturers that offer a full LC/MS/MS instrument that are proven within the forensic toxicology community. The GTSC adds that it compared the available LC/MS/MS instruments' relative cost, size, service and training packages, pre-existing methods, method transfer (within the forensic toxicology community), technical capability, software, LC and MS/MS compatibility, and country of origin. Although the features of the instruments vary, GTSC states that the critical needs for the FIC are size, pre-existing methods, and method transfer ability. First, the LC/MS/MS instrument must meet the available space in the FIC laboratory. According to the GTSC, the FIC plans to purchase a second instrument within a few years to support additional casework. The GTSC identified three manufacturers (Waters, AB Sciex and Thermo Fisher Scientific) that produce an instrument that is small enough for two instruments to fit within the FIC laboratory. Second, the GTSC identified four manufacturers that have forensic toxicology packages that are included with the software, that contain pre-loaded methods that are already developed and are widely used in the toxicology community. According to GTSC, this last feature is critical since it will permit the FIC to communicate with other labs for assistance with methods and troubleshooting, which would save considerable time and resources. GTSC states that Waters, Agilent, AB Sciex and Thermo Fisher Scientific meet its pre-existing methods and transfer methods requirements.

NHTSA conducted similar assessments¹ and was unable to locate domestic manufacturers of LC/MS/MS instruments with the specifications required by GTSC. Based upon New York GTSC's and NHTSA's analysis, NHTSA is unaware of an LC/MS/MS instrument that is manufactured domestically. Since an LC/MS/MS instrument is unavailable from a domestic manufacturer and the equipment would improve blood-alcohol testing and reporting by increasing detection, reducing drug interference, and increasing processing speed to advance the purpose of 23 U.S.C. 405(d), a Buy America waiver is appropriate. NHTSA invites public comment on this conclusion.

We note that NHTSA highway safety grant funds are intended to support traffic safety programs in the States. The goal of the impaired driving countermeasures grant is to have States adopt and implement effective programs to reduce driving under the influence of alcohol, drugs, or the combination of alcohol and drugs. Activities and equipment fully funded and purchased using NHTSA 405(d) grant funds must be used solely to support this goal. For all funded activities and equipment that have both related and unrelated highway safety grant components, the Federal share is based proportionately on the projected use for the highway safety grant purpose. Therefore, if a State plans to use an item of equipment 50 percent of the time to support its federally funded traffic safety program and 50 percent of the time to support unrelated state programs, the NHTSA participation cannot exceed 50 percent of the total cost of the equipment.

In light of the above discussion, and pursuant to 23 U.S.C. 313(b)(2), NHTSA finds that it is appropriate to grant a waiver from the Buy America requirements to GTSC in order to purchase a LC/MS/MS instrument. This waiver is effective through fiscal year 2016 and expires at the conclusion of fiscal year 2016 (September 30, 2016). In accordance with the provisions of

¹ NHTSA conducted internet searches, reviewed manufacturer websites, public information, and reviewed several websites that catalog domestic-made products (www.usaonly.us; www.americansworking.com; www.madeinamericaforever.com; and www.madeinusa.org) to locate domestically made LC/MS/MS instruments.

Section 117 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy of Users Technical Corrections Act of 2008 (Pub. L. 110-244, 122 Stat. 1572), NHTSA is providing this notice as its finding that a waiver of the Buy America requirements is appropriate for the purchase of a LC/MS/MS instrument.

Written comments on this finding may be submitted through any of the methods discussed above. NHTSA may reconsider this finding if, through comment, it learns of additional relevant information regarding its decision to grant the GTSC waiver request.

This finding should not be construed as an endorsement or approval of any products by NHTSA or the U.S. Department of Transportation. The United States Government does not endorse products or manufacturers.

Authority: 23 U.S.C. 313; Pub. L. 110-161; Pub. L. 110-244.

Issued in Washington, DC on May 25, 2016, under authority delegated in 49 CFR 1.95.

Paul A. Hemmersbaugh,
Chief Counsel.

BILLING CODE 4910-59-P

[FR Doc. 2016-12834 Filed: 5/31/2016 8:45 am; Publication Date: 6/1/2016]